IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent Number

7,892,835

Issue Date:

February 22, 2011

Application Number

10/593,831

Confirmation No.:

3234

Applicant

Toshihiro AKAIKE, et al.

Filed

September 22, 2006

Title

PLURIPOTENT STEM CELL GROWING METHOD

TC/Art Unit

: 1633

Examiner:

Scott LONG

Docket No.

69719.000003

Customer No.

21967

MAIL STOP PATENT TERM EXT.

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Dear Sir:

Patentee submit a Request for Reconsideration of the Patent Term Adjustment under 37 C.F.R. § 1.705(d) of 481 days ("Request") indicated for the above-identified patent. It is respectfully requested that Patentee be granted a minimum patent term adjustment of <u>485 days</u>.

U.S. Patent No. 7,892,835 ("the '835 patent") issued within two-months of the date of this Request. Accordingly, as required by 37 C.F.R. § 1.705(d), this request is timely.

In accordance with 37 C.F.R. § 1.705(b)(1), please charge the fee set forth in 37 C.F.R. § 1.18(e) (\$200) to the undersigned's **Deposit Account No. 50–0206**. In the event any additional fees are required for consideration of this request, the U.S. Patent and Trademark Office ("USPTO") is authorized to charge these fees to the undersigned's Deposit Account No. 50–0206.

Remarks begin on page 2.

REMARKS

Patentee requests reconsideration under 37 C.F.R. § 1.705(d) of the patent term adjustment for the '835 patent. In view of the following, it is respectfully requested that Patentee be granted a minimum patent term adjustment of at least <u>485 days</u>.

Statement Under 37 C.F.R. § 1.705(b)(2)

The patent term adjustment ("PTA") under 35 U.S.C. § 154(b) listed on the face of the '835 patent is <u>481 days</u>. This determination is in error because the USPTO failed to take certain action within the time frame specified in 37 C.F.R. § 1.702(a) <u>and</u> failed to issue a patent within three years of the 371(b) date of the above-identified patent in accordance with 37 C.F.R. § 1.702(b).²

A. Calculation of PTA Under 37 C.F.R. § 1.703

The following facts are relevant for determining PTA for the '835 patent.

- March 23, 2004 Priority document JP 2004–085393 is filed.³
- September 22, 2006 U.S. Patent Application No. 10/593,831 is filed.⁴
- September 22, 2006 371(c) date assigned by USPTO to U.S. Patent Application No. 10/593,831.⁵
- September 23, 2006 national stage commenced under 35 U.S.C. § 371(b) (*i.e.*, 30 months from the priority date).⁶
- November 22, 2007 fourteen months from the 371(c) date of the application (*i.e.*, beginning of "A period").
- January 5, 2009 mail date of Restriction Requirement (i.e., end of "A period").
- September 23, 2009 three years from the 371(b) date of the application (*i.e.*, beginning of "B period").
- May 3, 2010 Request for Continued Examination filed (i.e., end of "B period").8

¹ See Exhibit A [first page of the '835 patent (*)].

² See also Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage Pursuant to 35 U.S.C. § 371 of September 9, 2009 (attached).

³ See Exhibit A [first page of the '835 patent at (30)].

⁴ See Exhibit B (Transmittal Sheet with USPTO date stamp).

⁵ See Exhibit A [first page of the '835 patent at (86)] and Exhibit C (USPTO Bibliographic Information).

⁶ See 35 U.S.C. § 371 and 37 C.F.R. § 1.702.

⁷ See Exhibit D (USPTO Transaction History).

1. "A" Periods Under 37 C.F.R. § 1.702(a)(2)

The number of days from the beginning of the "A period" (November 22, 2007, i.e., fourteen months from the 371(c) date of the application) to the end of the "A period" (January 5, 2009, i.e., the day a first office action was mailed) is 410 days. This is contrary to the USPTO's calculations.9

"B" Periods Under 37 C.F.R. § 1.702(b) 2.

The number of days from the beginning of the "B period" (September 23, 2009, i.e., three years from the 371(b) day of the application) to the end of the "B period" (May 3, 2010, i.e., the day a Request for Continued Examination was filed) is 222 days. This is contrary to the USPTO's calculations.¹⁰

3. **Delay Attributed to Applicant**

The USPTO calculated Patentee's delay in the '835 patent as 147 days. This is in agreement with the USPTO's calculations.11

4. PTA = (A Period + B Period) - Applicants Delay

The PTA should be calculated as follows:

A period = 410 days. See 1. above

B period = 222 days. See 2. above.

Applicants' delay = 147 days. See 3 above.

(410 + 222) - 147 = 485 days

Accordingly, Patentee respectfully request that the '835 patent be granted a minimum PTA of at least 485 days.

 ⁸ See Exhibit D (USPTO Transaction History).
 ⁹ See Exhibit E (USPTO Patent Term Adjustment).
 ¹⁰ See Exhibit D (USPTO Transaction History).
 ¹¹ See Exhibit E (USPTO Patent Term Adjustment).

CONCLUSION

In view of the above remarks, it is respectfully requested that this Request for Reconsideration of Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a minimum patent term adjustment of at least 485 days.

Respectfully submitted,

HUNTON & WILLIAMS LLP

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Date: April 22, 2011

By:

Robert C. Lampe, III Registration No. 51,914

Christopher J. Nichols, Ph.D. Registration No. 55,984

HUNTON & WILLIAMS LLP Intellectual Property Department 1900 K Street, N.W., Suite 1200 Washington, DC. 20006 (202) 955–1500 (telephone) (202) 778–2201 (facsimile)

Exhibit A U.S. Patent No. 7,892,835 (first page)



(12) United States Patent

Akaike et al.

(10) Patent No.:

US 7,892,835 B2

(45) Date of Patent:

Feb. 22, 2011

(54) PLURIPOTENT STEM CELL GROWING METHOD

(75) Inventors: Toshihiro Akaike, Tokyo (JP); Keiichi

Fukuda, Tokyo (JP); Masato Nagaoka, Kanagawa (JP); Uichi Koshimizu,

Osaka (JP)

(73) Assignee: Daiichi Sankyo Company, Limited,

Chuo-Ku, Tokyo (JP)

Subject to any disclaimer, the term of this (*) Notice:

patent is extended or adjusted under 35

U.S.C. 154(b) by 481 days.

(21) Appl. No.: 10/593,831

(22) PCT Filed: Mar. 23, 2005

(86) PCT No.: PCT/JP2005/006006

§ 371 (c)(1),

(2), (4) Date: Sep. 22, 2006

(87) PCT Pub. No.: WO2005/090557

PCT Pub. Date: Sep. 29, 2005

(65)**Prior Publication Data**

US 2007/0155013 A1 Jul. 5, 2007

(30)Foreign Application Priority Data

Mar. 23, 2004 (JP) 2004-085393

(51) Int. Cl.

C12N 15/09 (2006.01)(2006.01)C12N 5/06 C12N 5/08 (2006.01)

- (52) **U.S. Cl.** 435/455; 435/354; 435/366
- Field of Classification Search None See application file for complete search history.

(56)References Cited

FOREIGN PATENT DOCUMENTS

JP	2001061470 A	3/2001
WO	WO 01/51616	7/2001
WO	WO 01/66697 A2	9/2001
WO	WO 03/020920 A1	3/2003
WO	WO 03/087305	10/2003

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* cited by examiner

Primary Examiner—Scott Long (74) Attorney, Agent, or Firm-Hunton & Williams LLP

ABSTRACT (57)

A novel growing method is provided for pluripotent stem cells such as ES cells. The method of the invention is a pluripotent stem cell growing method and gene transfer method in which pluripotent stem cells are cultured under conditions that maintain their undifferentiated state and pluripotency, the method being characterized by using a liquid medium and a culturing vessel having immobilized or coated on a substrate solid phase surface a molecule which is adhesive to the pluripotent stem cells in a fixed concentration, to grow the pluripotent stem cells in a dispersed state while maintaining their undifferentiated state and pluripotency, without using feeder cells, or to transfer and express a gene therein.

13 Claims, 12 Drawing Sheets

Exhibit BTransmittal Sheet with USPTO date stamp

IAP15 Rec'd PCT/PTO 22 SEP 2006

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

TTORNEY'S DOCKET NUMBER

58778.000007

U.S. APPLICATION NO. (If known, see 37 CFR 1.5), 10/5 93 8 641

INTERNATIONAL APPLICATION NO.			L APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED						
		_	JP2005/006006	23 March 2005	23 March 2004						
TITL	LE OF INVENTION										
	PLURIPOTENT STEM CELL GROWING METHOD										
APPI	APPLICANT(S) FOR DO/EO/US										
Tos	Toshihiro AKAIKE; Keiichi FUKUDA; Masato NAGAOKA and Uichi KOSHIMIZU										
App:	licant l	nerewi	ith submits to the United State	es Designated/Elected Office (DO/EO/US) the following items and other information:						
	\boxtimes	This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.									
		This	is a SECOND or SUBSEQU	ENT submission of items concerning a f	iling under 35 U.S.C. 371.						
-			express request to begin national (21) indicated below.	onal examination procedures (35 U.S.C. 3	771(f)). The submission must include items (5), (6),						
i	\boxtimes	The	US has been elected (Article :	31).							
,	\boxtimes	A co	py of the International Applic	eation as filed (35 U.S.C. 371(c)(2))							
		\boxtimes	is attached hereto (required	only if not communicated by the Internat	ional Bureau).						
			has been communicated by	the International Bureau.							
			is not required, as the applic	ation was filed in the United States Recei	iving Office (RO/US).						
	\boxtimes	An E	English language translation o	glish language translation of the International Application as filed (35 U.S.C. 371(c)(2)).							
		\boxtimes	is attached hereto.								
			has been previously submitt	ed under 35 U.S.C. 154(d)(4).							
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			have been communicated by		·						
			have not been made; howev	er, the time limit for making such amenda	ments has NOT expired.						
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				nent under 37 CFR 1.97 and 1.98.							
	\boxtimes				nce with 37 CFR 3.28 and 3.31 is included.						
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				ternational Application under 35 U.S.C.							
	⊠		r items or information:								
	Intern PCT/I	ationa IB/306	Search Report of PCT/JP2005/0	of a Change (Change of the Name of the 3rd As	cording of a Change (Change of the Person) (Form signee) (Form PCT/IB/306); PTO/SB/08 with 9 references;						

IAP9 Rec'd PCT/PTO 22 SEP 2006

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U.S. APPLICATION NO). (IF KNOWN, SEE 37 C	FR 1.7)	. INTERNATIONAL AF	PLICATION N	0.	ATTOR	NEY'S DOCKET N	UMBER
16/593831 The following fees have been submitted:			PCT	/JP2005/0	06006		58778.000	007
						CALC	CULATIONS	PTO USE
⊠ Ba	sic National Fee	(37 CFR 1.492(a))	\$ 300.00		\$	300.00	
⊠ Ex	amination Fee (3	7 CFR 1.492(c))						
If the written op	inion prepared by	ISA/US or the In	ternational Preliminary E			\$	200.00	
by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$ 0.00 All other situations \$ 200.00								
⊠ Sea	arch Fee (37 CFI	R 1.492(b))						
If the written o	pinion of the ISA	VUS or the Intern	ational Preliminary Exam	ination Re	enort prepared by			
IPEA/US indica	ites all claims sati	sfy provisions of F	CT Article 33(1)-(4)	\$ 0.00				
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All other situation		oo by the IB		\$ 500.00				
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☐ Additiona	l fee for specific	ation and drawing	s filed in paper over 100	sheets (ex	cluding sequence			
medium)	compliance with (37 CFR 1.492(j))	37 CFR 1.821(c) o:).	r (e) or computer program	listing file	d in an electronic			
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the date of comm	encement of the n	ational stage (37 C	CFR 1.492(h)) NUMBER EXTRA					-
Total claims	NOME	10 - 20 =	NUMBER EXTRA	x	* 50.00	\$ \$		
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Independent clair	ns	2 - 3 =		X	\$200.00	-		
MULTIPLE DEP	ENDENT CLAIN	M(S) (if applicable)	+	\$360.00	\$	360.00	
			TOTAL OF ABOV	E CALCU	LATIONS =	\$	1260.00	
☐ Applicant cl	aims small entity	status. See 37 CFI	R 1.27. The fees above are	reduced b	v 1/2	\$		
- 1-pp. coan claims small chitry status. See 57 CFR 1.27. The lees above are reduced by 1/2.						<u> </u>		
SUBTOTAL =						\$		
Processing fee of claimed priority d	f \$130.00 for fur late (37 CFR 1.49	nishing the Englis 2(f)).	th translation later than 3	0 months	from the earliest +	\$		
			ТОТА	L NATIO	NAL FEE =	\$		
Fee for recording appropriate cover	the enclosed assi sheet (37 CFR 3.	gnment (37 CFR 1 28, 3.31). \$40.00	.21(h)). The assignment	must be ac	companied by an	\$	40.00	
				FEES E	NCLOSED =	\$	1300.00	
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IAP9 Rec'd PCT/PTO 22 SEP 2006!

U.S.	APPLICA	ATION NO. (IF KNOWN, SEE 37 CFR 1.7)	72.4	INTERNATIONAL	APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
		10/5938	21	PC	CT/JP2005/006006		5878.00000	
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		Please charge Deposit Account No.		50-0206	in the amount of	\$	to cover the above fees.	
		A duplicate copy of this sheet is encl	losed.					
	\boxtimes	The Commissioner is hereby authori	zed to charge	any additional	fees which may be rec	juired, or c	redit any overpayment	
		to Deposit Account No. 5	0-0206	A dı	plicate copy of this she	eet is enclo	osed.	
		Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.						
		Where an appropriate time limit und granted to restore the application to			een met, a petition to	revive (37	CFR 1.137(a) or (b)) must be	
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Intellectual Property Department Hunton & Williams LLP				SIGNATURE				
1900 K Street, N.W.; Suite 1200 Washington, DC 20006-1109			Robert M. Schulman; Alexander H. Spiegler					
	(202)	955-1500 (telephone)		NAME				
	(202) 778-2201 (facsimile)			31,196; 5	6,625	Sep	tember 22, 2006	
			REGISTI	RATION NUMBER	DA'	TE		

Exhibit CUSPTO Bibliographic Information

10/593,831 PLU	RIPOTENT STEM CELL GROW	NG METHOD		04-22- 2011::09:44:5
Bibliographic Dat	a			
Application Number:	10/593,831	Customer Number:	21967	
Filing or 371 (c) Date:	09-22-2006	Status:	Patented Case	
Application Type:	Utility	Status Date:	02-02-2011	
Examiner Name:	LONG, SCOTT	Location:	ELECTRONIC	
Group Art Unit:	1633	Location Date:	-	
Confirmation Number:	3234	Earliest Publication No:	US 2007-0155013	A1
Attorney Docket Number:	69719.000003	Earliest Publication Date:	07-05-2007	
Class / Subclass:	435/455	Patent Number:	7,892,835	
First Named Inventor:	Toshihiro Akaike , Tokyo, (JP)	Issue Date of Patent:	02-22-2011	

Close Window

U.S. PATENT No. 7,892,835 ATTORNEY DOCKET NO: 69719.000003

Exhibit D USPTO Transaction History

10/593,831	PLURIPOTENT STEM CELL GROWING METHOD	04-22- 2011::09:36:5-
Transactio	n History	
Date	Transaction Description	
03-10-2011	Sequence Moved to Public Database	
02-22-2011	Recordation of Patent Grant Mailed	
02-02-2011	Issue Notification Mailed	
02-22-2011	Patent Issue Date Used in PTA Calculation	
01-18-2011	Dispatch to FDC	
01-14-2011	Application Is Considered Ready for Issue	
01-13-2011	Issue Fee Payment Verified	
01-13-2011	Issue Fee Payment Received	
11-09-2010	Sequence Forwarded to Pubs on Tape	
10-20-2010	Mail Examiner Interview Summary (PTOL - 413)	
10-20-2010	Mail Examiner's Amendment	
10-20-2010	Mail Notice of Allowance	
10-15-2010	Document Verification	
10-15-2010	Notice of Allowance Data Verification Completed	
10-15-2010	Case Docketed to Examiner in GAU	
10-15-2010	Examiner's Amendment Communication	
09-29-2010	Examiner Interview Summary Record (PTOL - 413)	
09-23-2010	Date Forwarded to Examiner	
09-21-2010	Response after Non-Final Action	
09-21-2010	Request for Extension of Time - Granted	
08-18-2010	Mail Examiner Interview Summary (PTOL - 413)	
08-16-2010	Examiner Interview Summary Record (PTOL - 413)	
05-27-2010	Mail Non-Final Rejection	
05-27-2010	Mail Examiner Interview Summary (PTOL - 413)	
05-27-2010	Non-Final Rejection	
05-03-2010	Information Disclosure Statement considered	
05-24-2010	Examiner Interview Summary Record (PTOL - 413)	
05-03-2010	Information Disclosure Statement (IDS) Filed	
05-03-2010	Information Disclosure Statement (IDS) Filed	
05-05-2010	Date Forwarded to Examiner	
05-03-2010	Request for Continued Examination (RCE)	
05 05 2010	B: DOE (ODA / B130	

Disposal for a RCE / CPA / R129

Workflow - Request for RCE - Begin

Mail Final Rejection (PTOL - 326)

Response after Non-Final Action

Date Forwarded to Examiner

Mail Non-Final Rejection

Non-Final Rejection

Final Rejection

Request for Extension of Time - Granted

Request for Extension of Time - Granted

Information Disclosure Statement considered

05-05-2010

05-03-2010

05-03-2010

11-02-2009

10-28-2009

09-13-2009

07-20-2009

07-20-2009

03-18-2009

03-16-2009

10-01-2007

09-22-2006	Information Disclosure Statement considered
02-04-2009	Date Forwarded to Examiner
02-02-2009	Response to Election / Restriction Filed
01-05-2009	Mail Restriction Requirement
01-02-2009	Restriction/Election Requirement
10-01-2007	Information Disclosure Statement (IDS) Filed
10-09-2007	Case Docketed to Examiner in GAU
10-01-2007	Information Disclosure Statement (IDS) Filed
07-05-2007	PG-Pub Issue Notification
09-22-2006	Information Disclosure Statement (IDS) Filed
04-23-2007	Application Dispatched from OIPE
09-23-2006	371 Completion Date
03-26-2007	Sent to Classification Contractor
03-26-2007	Notice of DO/EO Acceptance Mailed
10-21-2006	Cleared by OIPE CSR
10-10-2006	CRF Is Good Technically / Entered into Database
09-22-2006	CRF Disk Has Been Received by Preexam / Group / PCT
09-22-2006	Initial Exam Team nn

Close Window

U.S. PATENT No. 7,892,835 ATTORNEY DOCKET No: 69719.000003

Exhibit EUSPTO Patent Term Adjustment

10/593,831 PLURIPOTENT STEM CELL GROWING METHOD					04-22- 2011::0	09:37:23
Patent T	erm Adjı	ustments				
Patent Te	rm Adjustr	nent (PTA) for Appl	ication Number: 10/593,831			
Filing or 3	371(c) Date	e: 09-22-2006	Overlapping Days Between {A and	B} or {A ar	nd C}:	0
Issue Dat	e of Patent	: 02-22-2011	Non-Overlapping USPTO Delays:			628
A Delays:		409	PTO Manual Adjustments:			0
B Delays:		219	Applicant Delays:			147
C Delays:		0	Total PTA Adjustments:			481
Patent Te	erm Adjus	tment History	Explanation Of Calculations			
Number	Date	Contents Descri	ption	PTO (Days)	APPL (Days)	Start
66.5	05-02- 2010	PTA 36 Months		219		66.4
66.4	09-25- 2006	Commencement I	Date			0
66	02-22- 2011	Patent Issue Date	e Used in PTA Calculation			0
65	01-19- 2011	Export to Final Da	ata Capture			0
64	01-18- 2011	Dispatch to FDC	Dispatch to FDC			
63	01-14- 2011	Application Is Cor	Application Is Considered Ready for Issue			0
62	01-13- 2011	Issue Fee Paymer	nt Verified			0
61	01-13- 2011	Issue Fee Paymer	nt Received			0
60	12-21- 2010	Finished Initial Da	ata Capture			0
59	11-09- 2010	Sequence Forward	ded to Pubs on Tape			0
58	10-25- 2010	Export to Initial D	ata Capture			0
55	10-20- 2010	Mail Notice of Allo	wance			0
54	10-15- 2010	Document Verifica	ation			0
53	10-15- 2010	Issue Revision Co	mpleted			0
52	10-15- 2010	Notice of Allowand	ce Data Verification Completed			0
51	10-15- 2010	Case Docketed to	Examiner in GAU			0
48	10-15- 2010	Examiner's Amend	dment Communication			0
47	09-29- 2010	Examiner Intervie	w Summary Record (PTOL - 413)			0

46	10-13- 2010	Allowability Notice		0
45	09-23- 2010	Date Forwarded to Examiner		0
44	09-21- 2010	Response after Non-Final Action	25	40
43	09-21- 2010	Request for Extension of Time - Granted		0
42	08-18- 2010	Mail Examiner Interview Summary (PTOL - 413)		0
41	08-16- 2010	Examiner Interview Summary Record (PTOL - 413)		0
40	05-27- 2010	Mail Non-Final Rejection		0
39	05-27- 2010	Mail Examiner Interview Summary (PTOL - 413)		0
38	05-27- 2010	Non-Final Rejection		0
37	05-03- 2010	Information Disclosure Statement considered		0
35	05-24- 2010	Examiner Interview Summary Record (PTOL - 413)		0
34	05-03- 2010	Information Disclosure Statement (IDS) Filed		0
33	05-03- 2010	Information Disclosure Statement (IDS) Filed		0
32	05-05- 2010	Date Forwarded to Examiner		0
31	05-03- 2010	Amendment Submitted/Entered with Filing of CPA/RCE		0
30	05-03- 2010	Request for Continued Examination (RCE)	90	26
29	05-05- 2010	Disposal for a RCE / CPA / R129		0
28	05-03- 2010	Request for Extension of Time - Granted		0
27	05-03- 2010	Workflow - Request for RCE - Begin		0
26	11-02- 2009	Mail Final Rejection (PTOL - 326)		0
25	10-28- 2009	Final Rejection		0
24	09-13- 2009	Date Forwarded to Examiner		0
23	07-20- 2009	Response after Non-Final Action	32	21
22	07-20- 2009	Request for Extension of Time - Granted		0
21	03-18- 2009	Mail Non-Final Rejection		0

20	03-16- 2009	Non-Final Rejection		0
19	10-01- 2007	Information Disclosure Statement considered		0
17	02-04- 2009	Date Forwarded to Examiner		0
16	02-02- 2009	Response to Election / Restriction Filed		0
15	01-05- 2009	Mail Restriction Requirement	409	7
14	01-02- 2009	Restriction/Election Requirement		0
13	10-01- 2007	Information Disclosure Statement (IDS) Filed		0
12	10-09- 2007	Case Docketed to Examiner in GAU		0
11	10-01- 2007	Information Disclosure Statement (IDS) Filed		0
10	07-05- 2007	PG-Pub Issue Notification		0
8	04-23- 2007	Application Dispatched from OIPE		0
7	09-23- 2006	371 Completion Date		0
6	03-26- 2007	Sent to Classification Contractor		0
5	03-26- 2007	Notice of DO/EO Acceptance Mailed		0
4	10-21- 2006	Cleared by OIPE CSR		0
3	10-10- 2006	CRF Is Good Technically / Entered into Database		0
0.5	03-23- 2005	International Filing date		0

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Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage

Pursuant to 35 U.S.C § 371

Summary: The computer program that the United States Patent and Trademark Office (USPTO) uses to calculate patent term adjustment incorrectly calculates the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications if the requirements of 35 U.S.C. § 371 are not fulfilled on the date that the national stage commenced under 35 U.S.C. § 371(b) or (f). The USPTO is in the process of correcting this computer program. Applicants seeking a revised patent term adjustment determination based on this calculation must submit a timely request for reconsideration of the patent term adjustment indicated in the patent under 37 CFR 1.705(d).

Background: Under 35 U.S.C. § 154(b)(1)(B), an applicant is entitled to additional patent term adjustment if the issue of an original patent is delayed due to the failure of the USPTO to issue a patent within three years after the actual filing date of the application. The USPTO implemented the three-year pendency provision in 35 U.S.C. § 154(b)(1)(B) in 37 CFR 1.702(b) and 37 CFR 1.703(b). See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 56365, 56391-92 (Sept. 18, 2000) (final rule). The USPTO indicated the three-year pendency provision in 35 U.S.C. § 154(b)(1)(B) is measured from the date that the national stage commences under 35 U.S.C. § 371(b) or (f) in an international application. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. at 56382-84.

The USPTO makes patent term adjustment determinations by a computer program that uses the information recorded in the USPTO's automated patent application information system (the Patent Application Locating and Monitoring system or PALM system), except when an applicant requests reconsideration pursuant to 37 CFR 1.705. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. at 56370, 56380-81.

Discussion: The USPTO is in the process of correcting an error in the computer program that it uses to calculate the patent term adjustment that affects patents issuing from international applications entering the national stage as to the United States pursuant to 35 U.S.C. § 371. The USPTO's computer program incorrectly calculates the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications as being measured from the date that the requirements of 35 U.S.C. § 371 were fulfilled rather than the date the national stage commenced under 35 U.S.C. § 371(b) or (f) in the international application. The USPTO is correcting the computer program to reflect that the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications is measured from the date the national stage commenced under 35 U.S.C. § 371(b) or (f) in the international application.

An applicant seeking a revised patent term adjustment determination based upon the three-year pendency provision must submit a timely request for reconsideration of the patent term adjustment indicated in the patent. The USPTO does not calculate and inform the applicant of the patent term adjustment based upon the three-year pendency

provision of 35 U.S.C. § 154(b)(1)(B) in the notice of allowance because the USPTO must know the date the patent will issue to be able to calculate the patent term adjustment based upon this provision. Thus, reconsideration of the patent term adjustment indicated in the patent as it relates to the three-year pendency provision of 35 U.S.C.

§ 154(b)(1)(B) is **not** considered a matter that could have been raised in an application for patent term adjustment under 37 CFR 1.705(b) (provides for reconsideration of the patent term adjustment indicated in the notice of allowance). Therefore, a request for reconsideration of the patent term adjustment calculation based on the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) will be considered timely under 37 CFR 1.705(d) if filed within two months of the date the patent issued.

For Further Information Contact: The Office of Patent Legal Administration by telephone at (571) 272-7702, or by mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: 9/9/09

David J. Kappos

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office